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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,324	12/15/2001	Christopher Thomas Walsh	55046 (70207)	8192

21874 7590 05/18/2006

EDWARDS & ANGELL, LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
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NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/017,324	WALSH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nashaat T. Nashed, Ph. D.	1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53,55 and 59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-53, 55, and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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The application has been amended as requested in the communication filed February 21, 2006. Accordingly, claims 4, 10, 12, 14, 18, 34, 37, and 59 have been amended.

Claims 1-53, 55, and 59 are pending.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 12-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (a) The phrase "N-C<sub>2</sub>-C<sub>6</sub>alkanoylC<sub>2</sub>-C<sub>6</sub>aminoalkyl" in claims 12-33 renders the claims indefinite for the reasons set forth in the prior Office actions mailed 1/30/04, 1/13/05, and 8/18/05.

In response to the above rejection, applicants continue to traverse the rejection on the ground that the phrase is a standard IUPAC nomenclature.

Applicants' arguments filed 8/18/06 have been fully considered, but they are found unpersuasive. The examiner disagrees for reasons of record. Applicant should provide a prior art article showing the use of the formula.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-53, 55 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office actions mailed 1/30/04, 1/13/05, and 8/18/05.

In response to the above rejection, applicants traverse the rejection and repeated their previous arguments.

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Applicants' arguments filed 2/21/06 have been fully considered, but they are found unpersuasive for reasons of record. All 17 peptides listed in Table 1 are tyrocidine A homologous series and cyclized by the thioesterase domain of tyrocidine synthase. Two of the seventeen peptides failed to cyclize. The thioesterase domain used for the cyclization reaction clearly displays substrate specificity. Every other thioesterase domain is expected to display substrate selectivity. The specification fails to describe a structure activity relationship between the substrate to be cyclized and the thioesterase or the thioesterase domain to be used for the cyclization reaction. At page 18, third paragraph, applicants allege that substrates for each of the identified thioesterase domain provided by the specification are known such that homologues substrate suitable for macrocyclization by a specified excised thioesterase domain can be rationally designed. The problem with applicant argument is that: (a) one of ordinary skill in the art would not know which other thioesterase domain can function on its own as an excised fragment, the specification provides one example; and (b) the rational in the rational design is not taught in the specification. In another word, applicants are arguing that the ordinary skill in the art is capable of providing a new invention.

Claims 34-53, and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office actions mailed 1/30/04, 1/13/05, and 8/18/05.

In response to the above rejection, applicants repeated his previous arguments and argue that claim 34 is exemplified by the method of synthesis of gramicidin S from a pentapeptide precursor.

Applicants' arguments filed 2/21/06 have been fully considered, but they are found unpersuasive for reasons of record. The examiner regrets over looking the example of the dimerization of the pentapeptide catalyzed by tyrocidine thioesterase domain to produce gramicidin S. While this species of the invention is properly described, the description for the entire genus is not. Indeed, the specification have described the reasons for selecting the pentapeptide because of its similarity to the substrate for tyrocidin thioesterase domain, but the specification does not provide teaching on the selection of both the enzymes and substrate, or provide several other working examples showing that the method is general in nature and can be applied in most cases.

Claims 1-53, 55, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

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the invention for the reasons set forth in the prior Office action mailed 1/30/04 and 1/13/05, and 8/18/05.

In response to the above rejection, applicants continue to argue that the specification is fully in compliance with the enablement requirement.

Applicants' arguments filed 2/21/06 have been fully considered, but they are found unpersuasive for reasons of record. As indicated in the previous Office action, conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action. Applicants have not provided any evidence that rebut a *prima facie* case of non-enablement. It is true that the modification of polyketide synthase system would enable the said synthase to produce new compound, but there is large volume of art that support Trauger *et al.* statement since the mid 1990's. The instant case is quite different from modifying a polyketide synthase. It requires removing all other modules and domains from the polyketide synthase, and use only the thioesterase domain as a functional enzyme by itself.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Nashed", with a stylized flourish above the letters.

Nashaat T. Nashed, Ph. D.  
Primary Examiner  
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